

### **REMARKS**

Claims 3, 8-9, 12, 15 and 17-19 have been amended. Support for the amendments can be found throughout the specification and in originally filed claims 1, 3, 18 and 19. No new matter has been added. Claims 1 and 2 have been cancelled. Applicants reserve the right to prosecute the cancelled subject-matter at a later date.

Applicants thank the Examiner for withdrawing the previous objection to the Figures and the previous rejections of claims under 35 U.S.C. § 101, 112, and 102(b). See Office Action at p. 2.

Claims 3, 8-10 and 12-26 are pending.

### **CLAIM REJECTIONS**

#### ***Rejection under 35 U.S.C. § 101***

The Examiner has rejected claims 1-3, 8-10, 12-17 and 26 under 35 U.S.C. § 101 as being “directed to non-statutory subject matter.” See Office Action at p. 2. In an effort to expedite prosecution and not in acquiescence to the rejection, claims 1 and 2 have been cancelled thus rendering this rejection moot. Applicants respectfully request the withdrawal of this rejection. Claims 8-10, 12-17 and 26 depend from independent claim 3.

Specifically, the Examiner alleges that the above-mentioned claims read “on products of nature because products of nature may contain dead and live cells.” *Id.* Applicants respectfully traverse this rejection. Claim 3 has been amended to specify that the pharmaceutical composition also includes a pharmaceutically acceptable carrier, diluent or excipient. Applicants respectfully submit that claim 3 does not read on naturally occurring bacteria. Applicants respectfully request the withdrawal of this rejection with respect to claim 3 and claims dependent therefrom.

#### ***Rejection under 35 U.S.C. § 102(b)***

The Examiner has maintained the rejection of claims 1-3 and 8-10 under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No 4,599,310 to Matson et al. (“Matson”). See

Office Action at p. 2. Claims 1 and 2 have been cancelled thus rendering this rejection moot with respect to those claims. Claims 8-10 depend from independent claim 3.

Claim 3 relates to a pharmaceutical composition that includes  $10^4$  to  $10^{10}$  killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides* and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modifies a cellular immune response.

Matson describes an antibiotic (sandramycin) produced by fermentation of a *Nocardioides* strain and further describes purifying sandramycin and the uses of this purified antibiotic. See col. 2, lines 58-60, col. 7, line 41 to col. 8, line 64, and col. 10, line 62 to col. 12, line 25. Matson does not describe a pharmaceutical composition that includes  $10^4$  to  $10^{10}$  killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioides* and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modifies a cellular immune response. Indeed, in Matson, the antibiotic is isolated from a culture and the antibiotic is administered to patients. See col. 7, line 42 to col. 8, line 63 and col. 12, lines 9-25. Matson does not administer bacterial cells to patients. Matson describes cultivating cells for the production of an antibiotic. See col. 1, line 6 to col. 7, line 40.

Accordingly, independent claim 3 is not anticipated by Matson. Claims 8-10 depend from claim 3 and are also not anticipated by Matson for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

#### ***Rejection under 35 U.S.C. § 112***

The Examiner has rejected claims 18-25 under 35 U.S.C. § 112, second paragraph for being indefinite "for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." See Office Action at p. 3. Specifically, the Examiner rejects these claims for being "dependent from rejected claims." Id.

In effort to expedite prosecution, Applicants have amended claims 18 and 19 to be independent claims. Claims 20-22 depend from newly independent claim 18 and claims 23-25 depend from newly independent claim 19. Thus, claims 18-25 are allowable.

**CONCLUSION**

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance. A petition for a two month extension of time is enclosed. Should any further fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account 19-4293.

Respectfully submitted,

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